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Defendants Healthcare Associates of Texas, LLC (“HCAAT”), Healthcare Associates of Irving, LLP (“HCAI”), David Harbour, Jeff Vines, Kristian Daniels, Dr. Charles L. Powell, Dr. David Deems, Dr. Walter Gaman, and Dr. Terrence Feehery (collectively, “Defendants”) submit this Response in Opposition to Relator Cheryl Taylor’s motion to exclude Defendants’ experts Alice Gosfield, Esq., Daniel Shay, Esq., Tony Cobos, Esq., and Gregory Russo (ECF 457), and state as follows:

INTRODUCTION

Relator’s multi-pronged attack on the opinions offered by Defendants’ experts are universally unfounded. Relator takes issue with the opinions of Alice Gosfield, Daniel Shay, and Tony Cobos primarily because they are trained attorneys, which alone is not a valid basis to exclude expert testimony. Relator’s motion fails to provide any other reason to contest Cobos’s qualifications to opine as an expert in this case. As discussed in more detail below, Gosfield has over 50 years of experience advising physicians practices and is a well-established and trusted expert throughout the healthcare industry. Shay similarly has decades of experience advising physician practices on issues involving credentialing, enrollment, and reassignments—the very issues he opines on in this case. And contrary to the slanted representations in Relator’s motion, these experts are not “offering purely legal conclusions” but are instead opining, based on their respective knowledge and experience, on whether HCAAT’s practices were consistent with industry standards and reasonable in light of the regulatory guidance.

Relator does not dispute that Russo is qualified to testify as an expert nor does she contest the importance of having an expert like Russo to help the jury understand the amass of claims data relevant to the key issues in this case. Rather, Relator’s challenges solely go to the weight of Russo’s opinion, not its admissibility, and thus are not the proper subject of a Rule 702 motion. Even if Relator’s challenges were in the appropriate forum, as discussed below, Russo cited to accurate and reliable data, adopting a reasonable and well-accepted methodology for analyzing claims data.

ARGUMENT

Under Federal Rule of Evidence 702, “[a] witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if[:] . . . (a) the expert’s scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.” Fed. R. Evid. 702; *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993).

The proponent of the expert does not have to demonstrate that the testimony is correct, only that the expert is qualified, and that the testimony is relevant and reliable. *Moore v. Ashland Chem. Inc.*, 151 F.3d 269, 276 (5th Cir. 1998). Differences in expertise go to the weight of the testimony, rather than admissibility. *Huss v. Gayden*, 571 F.3d 442, 452 (5th Cir. 2009).

I. The Court should reject Relator’s argument that Gosfield’s, Shay’s, and Cobos’s opinions should be excluded because all three experts are highly qualified, their testimony will aid the jury in understanding a complex regulatory framework, and they only opined on whether HCAT’s practices were reasonable, not on whether HCAT’s practices were legal.

Relator argues that Gosfield and Shay should be excluded because they are not qualified, and that all three experts should be excluded because they are lawyers offering purely legal conclusions. ECF 457 at 1, 5. Beyond this argument, Relator did not contest that Cobos was qualified. Gosfield and Shay are similarly qualified to testify given that both experts boast decades of experience advising physician practices like HCAT on the relevant topics. Moreover, Relator ignores the fact that each expert’s testimony is necessary for enabling the trier of fact to understand the complicated Medicare and Texas regulatory framework. As for Relator’s argument that Gosfield, Shay, and Cobos are improperly rendering legal opinions, that is simply not true. All three experts only opined on whether HCAT’s practices were reasonable and consistent with industry standards. Moreover, Relator’s

argument ignores that courts examine the substance of the expert's statements, not merely the expert's credentials, when assessing whether an expert improperly rendered legal opinions.

A. Defendants' experts Gosfield and Shay are qualified to testify on the designated topics.

The Court should reject Relator's argument that Gosfield's and Shay's opinions should be excluded because they lack the requisite qualifications. ECF 457 at 5. Experts are qualified to provide opinions if they have **relevant** experience. *United States v. Brown*, 871 F.3d 352, 357 (5th Cir. 2017) (upholding a witness's qualification to serve as an expert "in Medicare and the practices of medical equipment providers" in a fraud case because the expert "worked for a Medicare claims-processing contractor," taught "the general practices and policies of both Medicare and payments to medical equipment companies," and "wr[ote] and edited manuals instructing suppliers on how to properly bill Medicare and comply with its guidelines").

Despite this well-established principle, Relator argues that Gosfield and Shay are not qualified because their "specific knowledge, training, and expertise" is derived from their representation of other clients within the healthcare industry (ECF 457 at 6). But Relator's argument is flawed for two reasons. First, Relator applies the wrong legal standard to support the exclusion of Gosfield and Shay. Specifically, Relator claims that attorneys can only serve as experts when they "possess some specific knowledge, training, and expertise **beyond representing other clients in an industry.**" *Id.* at 6 (emphasis added). For this proposition, Relator cites two unpublished decisions from other jurisdictions, *Bivins v. Stein* and *GeoDynamics, Inc. v. DynaEnergetics US, Inc.*, which simply do not support such a broad prohibition. *Id.* In *GeoDynamics*, the court found that a patent attorney could not provide expert testimony as to the validity of a patent because the lawyer's curriculum vitae did not reflect "education or experience that suggests he is a qualified technical expert in the relevant area." *GeoDynamics, Inc. v. DynaEnergetics US, Inc.*, No. 2:17-CV-00371-RSP, 2018 WL 5292659, at *1 (E.D.

Tex. Sept. 21, 2018).¹ This requirement that an expert possess a “technical expertise” is unique to patent experts, with no application to this case.² *Bivins* is equally distinguishable. In that case, the Eleventh Circuit affirmed the lower court’s decision to exclude a Florida litigator who was neither “a specialist in New York real estate law” nor an expert on guardianships, two crucial underpinnings of the case. *Bivins v. Stein*, 759 F. App’x 777, 781 (11th Cir. 2018). Thus, *GeoDynamics* and *Bivins* merely reaffirmed that an expert must have **relevant** experience that will aid the trier of fact; they did not impose additional qualifications for legal experts generally as Relator claims. As described in subsections (a) and (b) below, Gosfield and Shay both satisfy this basic requirement.

Second, even if expertise “beyond representing other clients in an industry” was required, Gosfield and Shay meet that requirement. Relator ignores that Gosfield and Shay have extensive relevant experience outside of advising physician practices, including publishing and lecturing extensively to non-client audiences as described in each of the dedicated sub-sections below.

1. Gosfield’s decades of relevant experience advising physician practices and aiding government agencies make her uniquely qualified to render opinions in this matter.

Gosfield’s testimony is admissible under Rule 702 because she possesses the requisite knowledge, experience, and training given her 50 years of experience advising physicians practices on the relevant topics. Fed. R. Evid. 702; *Brown*, 871 F.3d at 357. Gosfield opines on whether five HCAT practices were “reasonable and consistent with industry practices,” specifically: incident-to billing, enrollment and billing privileges, the use of standing orders, the rules applicable to group practices in billing for Annual Wellness Visits, the rules that were applicable to the services rendered in HCAT’s

¹ Even in this case cited by Relator, the court nonetheless permitted the attorney to opine on issues that he was qualified to discuss, further highlighting that the key inquiry in assessing an expert’s qualifications is whether the expert has relevant experience. *GeoDynamics, Inc.*, 2018 WL 5292659, at *1.

² *Brown*, 871 F.3d at 357 (noting that when an individual is offered as an expert on Medicare regulations and the practices of providers, “[t]his is not the type of cutting-edge scientific evidence for which the *Daubert* factors are often most vigorously contested”).

Physical Medicine Department. ECF 457 at 6; ECF 456-1, APP. 448 (Gosfield Report). Gosfield also opines on typical compliance programs for small group physician practices. ECF 456-1, APP. 447-448 (Gosfield Report). Relator argues that Gosfield is not qualified to opine on these topics and her testimony should be excluded in its entirety because she relies on legal principles and lacks knowledge of issues that are only tangentially related to these broader topics. This argument is baseless.

Gosfield is undoubtedly qualified to render opinions on whether these various practices were reasonable and common in the industry. She has 50 years of experience advising physician practices across the country on these complex federal regulations touching on medical staff issues, fraud and abuse, compliance, and reimbursement. ECF 456-1, APP. 488-510 (Gosfield Report). Through decades of advising physician practices, she has observed operations of entities similar to Defendants. Moreover, Gosfield is a well-established industry expert offering practice guidance for those in the healthcare industry. She has been published nearly 200 times and has given hundreds of presentations to a variety of organizations, including non-lawyers, on many aspects of healthcare billing. *Id.* at APP. 445-46. And even policymakers within the federal government, including the Department of Health and Human Services (“DHHS”) have requested Gosfield’s expertise on the practical implementation of laws and regulations.³ In short, it would be difficult to find someone who knows more about healthcare providers’ implementation of Medicare billing regulations than Gosfield. Accordingly, Relator’s argument that she is not qualified to opine on these issues is meritless.

Relator attempts to argue that Gosfield’s lack of familiarity with certain issues (that are at best only tangentially related to her opinions), require exclusion of her opinions. For instance, Relator takes issue with the fact that Gosfield did not review the Medicare Provider Enrollment, Chain, and

³ Specifically, Gosfield has assisted the Agency for Healthcare Research and Quality (“AHRQ”), which was formerly known as the Agency for Health Care Policy and Research, to analyze guidelines. This agency is part of DHHS. *See id.*, APP. 489 (Gosfield Report).

Ownership System (PECOS). PECOS is the online system used specifically by providers to manage their Medicare enrollment.⁴ ECF 457 at 3, 15. But prior to the latter exchange cited by Relator, in which Gosfield acknowledged that she has not personally utilized the PECOS online system, Gosfield explained that the PECOS system “demonstrates what the enrollment dates . . . are for providers”, thus showing that Gosfield was knowledgeable about PECOS, even if she had not personally pulled a provider’s enrollment dates from the system herself. ECF 456-1, APP. 00849 (Gosfield Dep. Tr. at 186:25-187:5). Gosfield further testified that she is familiar with the “theory of PECOS.” ECF 456-1, APP. 00849 (Gosfield Dep. Tr. at 188:22-23). Thus, Gosfield understands the meaning of PECOS data, which lists the providers enrollment date in Medicare. Regardless, Relator misses the point that obtaining login credentials to see when a provider was enrolled is a distinct issue from assessing whether a provider must be credentialed to perform certain services or bill services incident-to other physicians. *See, e.g.*, ECF 456-1, APP. 478 (Gosfield Report at 34) (offering her opinion that it was reasonable for HCAT to bill services performed by nurse practitioners incident-to a physician). Gosfield made it clear that she was “offering no opinion with regard to any individual provider in any way.” ECF 456-1, APP. 478 (Gosfield Depo. Tr. at 189:7-8). Thus, although Gosfield may not pull data directly from PECOS herself,⁵ that does not detract from her broader expertise regarding Medicare enrollment and retrospective billing dates, having spent decades advising physician practices on these issues and publishing on these topics as well.⁶

⁴ <https://pecos.cms.hhs.gov/pecos/login.do#headingLv1>.

⁵ According to the PECOS website, an individual can only get a PECOS account if they are “an Individual Practitioner, Authorized or Delegated Official for a Provider or Supplier Organization, or an individual who works on behalf of Providers or Suppliers.” Moreover, such an individual would presumably only have access to the PECOS data relevant to them individually or their practice, so it’s unclear why Relator believes that possessing such login credentials is a prerequisite for opining on credentialing requirements.

⁶ Co-author with Daniel F. Shay, “Medicare Enrollment: A Never-Ending High Hurdles Race,” *Dermatology World* (April 2011), pp. 14-16; “Medicare Enrollment: A Tougher Road to Go,” *ASNC*

As for Relator's argument that Gosfield cannot opine on federal regulations because she is not an expert on state laws that are referenced in these federal regulations, Relator fails to cite a single decision to support this proposition. The lack of support is not surprising given that such a holding would effectively eliminate the majority of healthcare experts from offering opinions in any healthcare False Claims Act case. Indeed, given that federal guidance in the healthcare industry often defers to state laws,⁷ by Relator's logic, any expert on federal healthcare laws must *also* be an expert on the healthcare laws of all 50 states.

Presumably Relator raised this issue in response to Defendants highlighting that Relator's experts failed to analyze Texas scope of practice provisions prior to concluding that HCAT could not provide physical medicine services. *See* ECF 456-1, APP. 25 (Cobos Report). But this is a false equivalence. It was not necessary for *every* HCAT expert to be familiar with Texas scope of practice provisions to opine on any matter relevant to the case. But, given that the Medicare Manual defers to state scope of practice provisions to determine whether physical medicine services could be covered under Medicare,⁸ it is important to have at least one expert who understood Texas scope of practice provisions to render an opinion on whether HCAT's practices were reasonable and common in the industry. Defendants do not dispute that Gosfield is not an expert on Texas scope of practice provisions, which is why she deferred to Cobos on this topic. *See* ECF 456-1, APP. 482 (Gosfield Report). But crucially, Relator failed to obtain any expert who could speak to how these scope of practice provisions operated in Texas. Gosfield's breadth of experience writing and presenting on matters related to Medicare regulations, and her extensive experience advising physician practices gives

Imaging Update (Mar-Apr 2011) p. 7; "The Legal Mandate for Credentialing and Privileging," American Group Practice Journal (Jan/Feb 1992) pp. 67-71.

⁷ *See Medicare Benefit Policy Manual* (Chapter 15 alone, which outlines the requirements for covering physical therapy services, among other topics, refers to state laws 73 times and compliance with state scope of practice provisions at least 25 times).

⁸ *See* ECF 456-1, APP. 25 (Cobos Report).

her specialized knowledge that will help the trier of fact understand evidence in this case.

2. Shay is qualified to render opinions on credentialing, enrollment, and reassignment because he has advised physician practices on this issue for over two decades.

Shay's testimony is admissible under Rule 702 because he has the requisite knowledge, training, and experience to opine on credentialing, enrollment, and reassignment of physicians and non-physician practitioners (i.e., physician assistants and nurse practitioners) in Medicare given his 20 years of experience advising physician practices on this very issue. Fed. R. Evid. 702. Despite Shay's extensive experience, Relator argues that Shay is not qualified to opine on these topics because Shay does not work on these issues exclusively and because Shay acknowledged that he is unfamiliar with topics unrelated to his opinions.

As set forth in his expert report, Shay is designated to opine on Medicare guidelines and recommendations on practitioner and supplier enrollment and reassignment. ECF 457 at 8; ECF 456-1, APP. 641-642 (Shay Report). Under Rule 702 he is clearly qualified to do so. He has been advising physician practices in on Medicare enrollment and the reassignment process for over twenty years. ECF 456-1, APP. 640 (Shay Report). He is also an accomplished healthcare author and speaker.⁹

Relator attempts to downplay Shay's achievements and experience by contending that Shay is not qualified to testify on Medicare credentialing and enrollment issues because Shay does not handle these issues *exclusively*. Specifically, Relator argues that "Shay is not a 'Medicare credentialing' attorney," but rather "a healthcare attorney whose practice sometimes touches on credentialing issues." ECF 457 at 8. But the breadth of Shay's law practice does not diminish the depth of his expertise on enrollment and credentialing issues. Shay has "developed a detailed understanding of the Medicare credentialing process through [his] extensive experience counseling physician group practices and others on these subjects and related matters." Shay Report at 8. Indeed, the curriculum

⁹ <https://www.gosfield.com/about-us/daniel-f-shay>.

vitae attached to his expert report lists several publications on Medicare enrollment and credentialing. ECF 456-1, APP. 675-680 (Shay Report).¹⁰ Moreover, the relevant inquiry is not whether Shay solely focuses on credentialing – it is whether Shay has relevant knowledge and expertise regarding credentialing. Given his 20 years of experience advising physician practices on credentialing, enrollment, and reassignment, as well as his numerous publications covering these same topics, there is no disputing that the answer to that question is yes.

Relator's attempts to discredit Shay are completely misplaced. For example, Relator contends that Shay is not a credentialing expert because he has not pulled data from PECOS himself. As previously discussed in regards to Gosfield, the act of pulling data from a credentialing system has no bearing on whether an individual has expertise with regards to credentialing requirements.

Relator further contends that Shay is not qualified to opine on PTANs¹¹ because he did not review the Medicare electronic claim forms that Defendants submitted. ECF 457 at 9-10.¹² But Relator misses the point that Shay was merely clarifying his scope of expertise. Shay was not asked to opine on this issue, nor does Shay claim that he is offering opinions on this matter.

¹⁰ Shay's resume lists a number of credentialing and enrollment publications including "Maintaining Medicare Enrollment: the Never-Ending High-Hurdles Race," NAMAS Payer Rules (February 28, 2020); "Maintaining Medicare Enrollment Data: Managing the Ongoing High-Hurdles Race," Compliance Today (January-February 2020) pp. 25-30; "The Ongoing Ordeal of Maintaining Medicare Enrollment," Dermatology World (March 2019) pp. 22-23; "The Medicare Part-B Enrollment Obstacle Course: It Hasn't Gotten Any Easier," HEALTH LAW HANDBOOK (2019 ed.); Shay, "Potential Problems Exist in the Medicare Enrollment Process," Medical Economics (November 25, 2011) pp. 55-57; Shay, "Successfully Navigating the Medicare Enrollment Appeals Process," Medical Economics (November 10, 2011) pp. 95-96; Shay, "Halt! Who Goes There?: Coping with the Continuing Crackdown in Medicare Enrollment," HEALTH LAW HANDBOOK (2011 ed.) pp. 71-102; "Medicare Enrollment: Staying in the Game, Even When the Rules Change," Family Practice Management (March/April 2010) pp. 35-37; "Enrollment in Medicare: Fraternity Hazing or Keeping Out Bad Actors?" HEALTH LAW HANDBOOK (2009 ed.) pp. 1-34.

¹¹ "PTAN" stands for the Provider Transaction Access Number. It is also sometimes referred to as the Medicare Identification Number. *See* ECF 456-1, APP. 646 (Shay Report).

¹² In selectively quoting from Shay's deposition, Relator omits Shay's response that he referred to the Medicare manuals and their instructions on completing paper claim forms in reaching his opinions. ECF 456-1, APP. 1014 (Shay Dep. Tr. at 275:22-276:2).

Ultimately, Relator misconstrues the proper standard for assessing an expert's qualifications, as evidenced by Relator's interpretation of *GNC Power, LLC v. HITT Contracting Inc.* and *United States v. Organon USA Inc.*, both of which merely reiterate that experts must have **relevant** experience. ECF 457 at 10. In *GNC*, the expert was a mechanic specifically asked to opine on the functioning of a generator set. *GNC Power, LLC v. HITT Contracting Inc.*, No. 3:09-CV-0491-P, 2010 WL 11561924, at *2 (N.D. Tex. July 13, 2010). The court held that the mechanic was not qualified because he "had no formal training regarding generator sets and had only been working on generator sets for a few months" nor did he know anything about the test that he used to evaluate the generator. *Id.*

Similarly, in *Organon*, the court held that the expert attorney was not qualified to testify because he simply did not have experience in the relevant field. *United States v. Organon USA Inc.*, No. CV 07-12153-RWZ, 2015 WL 10002943, at *2 (D. Mass. Aug. 17, 2015). The fact that the expert in *Organon* was found to be an "undisputed subject matter expert on the intricacies of the Stark Law" in another case did not remedy that the expert had never worked in the pharmaceutical industry, which was at issue in the litigation.

Unlike *GNC* and *Organon* where the proffered experts had no experience on the topics they were asked to opine on, here Shay boasts two decades of relevant healthcare experience, including advising practices on credentialing requirements and authoring numerous publications on the topic. His expertise in this area will assist the trier of fact. Lastly, even if there were any gaps in his qualifications or knowledge (and there are not), those gaps would go to the weight of his testimony, not its admissibility because Rule 702 favors admissibility over exclusion. Fed. R. Evid. 702; *United States v. 14.38 Acres of Land*, 80 F.3d 1074, 1077 (5th Cir. 1996).

B. The opinions of Gosfield, Shay, and Cobos will aid the jury in understanding a complex regulatory framework.

Relator argues that the opinions of Gosfield, Shay, and Cobos should be excluded because "they are lawyers offering purely legal conclusions." ECF 457 at 5. In particular, Relator takes issue

with the fact that the experts “predominantly cite statutes and regulations throughout their reports” and opine on what the various regulations and rules require. *Id.* at 2-3.

Relator’s argument is flawed for multiple reasons. First, as Relator acknowledges (ECF 457 at 2), the Fifth Circuit has recognized that “merely being a lawyer does not disqualify one as an expert witness.” *Askanase v. Fatjo*, 130 F.3d 657, 672 (5th Cir. 1997). Moreover, courts routinely permit experts to offer testimony that references the Medicare regulations or Texas law. *United States v. Abdallah*, 629 F. Supp. 2d 699, 750 (S.D. Tex. 2009) (finding expert testimony on Medicare rules and regulations was both relevant and reliable).

Second, there is ample case law establishing that lawyers may serve as experts, provided they have knowledge and experience in the relevant field. *See, e.g., United States ex rel. Heller v. Guardian Pharmacy of Atlanta, LLC*, No. 1:18-CV-03728-SDG, 2023 WL 11909741, at *15 (N.D. Ga. Sept. 30, 2023), *motion to certify appeal denied*, No. 1:18-CV-03728-SDG, 2024 WL 102211 (N.D. Ga. Jan. 9, 2024) (holding that a healthcare lawyer was a qualified expert on Anti-Kickback Statute (“AKS”) compliance, in part, because of the expert’s prior experience drafting advisory opinions on AKS risk areas).

More importantly, Gosfield, Shay, and Cobos do not render opinions on the legality of HCAT’s practices.¹³ They only render opinions on whether, based on their experience advising physician practices, HCAT’s practices were reasonable and consistent with industry standards and reasonable in light of the regulatory guidance. *See, e.g., Cobos Report* at APP. 18 (Cobos Report) (finding that HCAT’s delegation of various tasks to medical assistants “was [c]onsistent with [g]enerally [a]ccepted [p]ractice in Texas”); *Id.* APP. 479 (Gosfield Report) (finding that HCAT’s incident-to billing practices were “reasonable and consistent with industry practices”); *Id.* APP. 644

¹³ This is in stark contrast to Relator’s experts who freely rendered legal opinions. *See, e.g., APP. 345* (Lalla Rebuttal at 4) (arguing that HCAT’s process of allowing medical assistants to order tests pursuant to standing delegation orders “did not comply with several Medicare rules”); *APP. 280* (Scott Rebuttal at 14) (claiming that “HCAT did not comply with Medicare’s incident-to requirements”).

(Shay Report) (“HCAT’s approach to assigning practitioners to PTANs was reasonable and consistent with a common approach in the industry.”).

In short, courts focus on the substance of an expert’s statement and routinely admit the opinions of legal experts, while excluding the opinions of non-legal experts for impermissibly rendering legal conclusions. *Compare Guardian Pharmacy of Atlanta, LLC*, 2023 WL 11909741, at *15 (admitting the testimony of a legal expert on AKS compliance), *with Adams v. New England Scaffolding, Inc.*, No. CV 13-12629-FDS, 2015 WL 9412518, at *6, *9 (D. Mass. Dec. 22, 2015) (declining to allow a non-legal expert to offer “conclusions concerning the legal elements of plaintiff’s negligence claim” and noting that an expert’s “interpretation of an ambiguous or unclear law” is not admissible).

Moreover, given the numerous and frequently changing regulations that HCAT was subject to, Gosfield’s, Shay’s, and Cobos’s opinions are necessary for helping the jury understand this complicated regulatory framework. *Adams*, 2015 WL 9412518, at *5 (noting that “[w]e live in a highly complex and often bureaucratic society” and expert testimony to explain this “regulatory environment . . . may be helpful to the jury to understand the issues in the case”). Courts recognize that in cases involving such an “intricate regulatory landscape,” such expert testimony is not only permissible – it is arguably required for a party to prove their case. *See United States v. Elfenbein*, No. JKB-22-0146, 2023 U.S. Dist. LEXIS 227183, at *86 (D. Md. Dec. 21, 2023) (acquitting a defendant accused of defrauding a health care benefit program because the plaintiff provided no expert testimony to help the jury understand a “complex set of rules” within the healthcare regulatory framework that the court noted did not comport with common sense); *United States v. Offill*, 666 F.3d 168, 175 (4th Cir. 2011) (noting that it is “difficult to imagine how the government could have presented its case . . . without the assistance of expert testimony to explain the intricate regulatory landscape”); *In re Fosamax Prod. Liab. Litig.*, 645 F. Supp. 2d 164, 191 (S.D.N.Y. 2009) (declining to exclude an expert from testifying because the expert’s “assessment of the reasonableness of [defendant’s] conduct in light of her experience and

her understanding of FDA regulations will be helpful to the jury”).

Defendants’ experts provided the background information necessary for understanding Texas and Medicare’s complex regulatory framework. Whether HCAT providers were enrolled with Medicare at the time of rendering care, for example, remains a factual dispute that will ultimately be resolved by the trier of fact.

C. The opinions of Gosfield, Shay, and Cobos involve questions of fact rather than purely legal matters.

Qualified experts are permitted to offer opinion testimony as to industry standards as long as such opinions involve questions of fact rather than purely legal matters. *Waco Int’l, Inc. v. KHK Scaffolding Houston, Inc.*, 278 F.3d 523, 533 (5th Cir. 2002). Courts permit this testimony because it allows the trier of fact to assess relevant elements of a case, such as intent. *Clingman & Hanger Mgmt. Assocs., LLC v. Knobel*, No. 16-62028-CIV, 2018 WL 11459532, at *6 (S.D. Fla. May 8, 2018) (holding that expert testimony regarding “industry custom and practice” was relevant because “[e]vidence that Defendants did not act consistent with industry custom and practice provides . . . ‘a basis from which the jury [can] evaluate the[ir] knowledge and state of mind’”). As discussed at length above, not all attorney experts necessarily offer legal opinions. Moreover, lawyers may testify as to legal matters when those matters involve questions of fact. *Askanase*, 130 F.3d at 672.

Here, Gosfield, Shay, and Cobos will testify as to standard, common, and typical practices across the industry, to aid the jury in determining questions of fact regarding the HCAT practices at issue in this case. Such testimony is crucial for assessing a key element of an FCA case: intent. Moreover, their testimony was grounded in the factual record, with each expert having reviewed multiple deposition transcripts and HCAT’s internal documents. Furthermore, and as described below, the testimony of Gosfield, Shay, and Cobos will assist rather than supplant the jury’s judgment. These experts will not instruct the fact finder on the governing law in this case, but will instead educate the jury on the healthcare industry that will contextualize the fact witnesses’ testimony.

1. Gosfield

Relator's characterization of Gosfield's expert testimony as simply that of a lawyer opining about "purely legal matters" (ECF 457 at 4) is baseless. Gosfield opined on industry standards and generally accepted practices. *See, e.g.*, ECF 456-1, APP. 448 (Gosfield Report) (opining that HCAT's incident-to billing practices were "reasonable and consistent with industry standards"). At no point did Gosfield render an opinion on the legality of HCAT's practices. Additionally, Gosfield's testimony regarding Medicare's rules and regulations, including the incident-to billing requirements and the use of protocols and standing orders will provide the framework and context for the fact witnesses to describe HCAT's operations. Moreover, these opinions are grounded in the factual record. For example, Gosfield opines that HCAT's PEP protocol was reasonable and common in the industry. ECF 456-1, APP. 485 (Gosfield Report). Relator's experts clearly disagree. *See, e.g.*, APP. 345 Lalla Rebuttal at 4.

In forming her opinions, Gosfield made it clear that she was relying on the evidence and testimony available in this matter. *See* ECF 456-1, APP. 469-473 (Gosfield Report). As noted in her appendix, prior to reaching her conclusions, Gosfield reviewed multiple deposition transcripts as well as discovery responses. Moreover, in the PEP section of Gosfield's report, she explains that she reviewed HCAT's standing delegation orders. Relying on her 50 years of experience working with practices like HCAT's, Gosfield opines that HCAT's orders helped standardize patient care. *Id.* Gosfield then utilizes her Medicare expertise to review the guidance from CMS on standing orders before ultimately concluding that such orders were reasonable. *Id.* at APP. 485 (Gosfield Report).

Whether the PEP protocols were in fact standing delegation orders and whether these orders were reasonable and consistent with industry standards remains a question of fact that will ultimately be resolved by the jury. Moreover, none of Gosfield's opinions present the end of the relevant inquiry. A jury may find that, despite HCAT's practices being consistent with industry standards, HCAT

nonetheless failed to comply with Medicare's requirements. Moreover, a jury may find that failing to comply with these requirements constituted a False Claims Act violation. In short, there are a number of leaps a court would have to make to determine that Gosfield's opinions removed questions of fact and law from the jury. In contrast, such leaps are not necessary for finding that Relator's experts clearly overstepped these boundaries. *See* APP. 280 (Scott Rebuttal at 14) (claiming that "HCAT did not comply with Medicare's incident-to requirements"). It is clear that Gosfield's specialized knowledge about the relevant regulatory framework and experience advising physicians practices would be immensely helpful to a jury who is seeking to render an informed opinion on whether HCAT complied with the applicable requirements.

2. Shay

Similarly, Shay's testimony regarding credentialing and enrollment will provide the framework and context for fact witnesses to describe HCAT's operations, is grounded in the factual record, and will assist the trier of fact. Shay's Exhibit B makes it clear that prior to reaching any opinions, he conducted a thorough review of the factual record including reviewing the deposition transcripts of Heather Brown, Kristian Daniel, and Dr. Powell, as well as HCAT's internal documents. *See* ECF 456-1, APP. 681-690 (Shay Report Exhibit B). In one opinion, Shay addresses Relator's claim that a failure to reassign to a specific PTAN means that the claims for services at various practice locations are not reimbursable. ECF 456-1, APP. 644 (Shay Report). Shay puts this allegation into context, noting that in practice under Medicare reimbursement processes, a failure to reassign a specific PTAN would not typically affect the practice's reimbursement. *Id.* It is well established that experts can opine on such topics. *United States v. Strange*, 23 F. App'x 715, 717 (9th Cir. 2001) (holding "expert testimony regarding Medicare regulations and reimbursement procedures" is "entirely appropriate for an expert").

Crucially, if Shay's opinions on this matter were stricken, the jury would not have the benefit of insight from someone familiar with reimbursement processes and practices, other than Relator's

baseless assertion that Novitas “would not have paid for those services” if it had been aware of the PTAN issue. *See* ECF 405, APP. 958 (Lalla Report at 65). According, Shay’s opinions are necessary for helping the jury understand these complex issues.

3. Cobos

Notably, Relator’s do not contest Cobos’s qualifications to opine as an expert in this case. Cobos’s opinions regarding how various Texas provisions regulating physical medicine and standing delegation orders operate in Texas provides the framework and context for fact witnesses to describe HCAT’s operations. Ultimately, his specialized knowledge will assist the jury in better understanding the facts and his opinions are grounded in the factual record.¹⁴

Cobos previously spent nearly a decade serving the Texas Medical Board, the state agency tasked with regulating the practice of medicine. *See* ECF 456-1, APP. 4 (Cobos Report). Cobos was directly involved in the “interpretation and application of statutory and agency rules related to supervision, scope of practice, delegation, and document requirements.” *Id.*, APP. 00005 (Cobos Report). Medicare’s coverage of services often depends on whether the provider is complying with various state laws, making Cobos’s opinions helpful to the trier of fact.

Indeed, Cobos provides the necessary background for understanding how the Texas regulatory framework intertwines with Medicare regulations. For example, neither party disputes that whether Medicare covers physical medicine services is at least partially dependent on whether the provider was permitted to do so according to Texas state law. Cobos’s report not only provides background on the Texas regulatory framework concerning physical medicine, but he also provides valuable insight into how the Texas Medical Board would evaluate this inquiry, noting that the Board

¹⁴ Cobos lists 31 documents that he reviewed that constituted HCAT’s standing delegation orders. ECF 456-1, APP. 18 (Cobos Report). Additionally, Cobos’s Appendix highlights that he reviewed the deposition transcripts of multiple HCAT staff members, including Dr. Powell and Dr. Feehery, as well as Relator’s deposition testimony. *Id.*, APP. 00039 (Cobos Report).

would expect a thorough review of medical records pursuant to the applicable Medicare Advantage Contractor (“MAC”) guidance. ECF 456-1, APP. 25 (Cobos Report). Crucially, Cobos does not opine on whether it was legal for HCAT’s nurse practitioners to provide physical medicine services, and he certainly does not opine on whether HCAT violated the FCA.

II. Russo is qualified; he relied on extensive data and his opinion is based on reliable methods.

Russo’s testimony is admissible under Rule 702. Relator does not dispute that Russo is qualified by knowledge, skill, experience, training, and education to testify in the form of an opinion. In addition, Russo satisfies all of the requirements of Rule 702 to offer his opinion testimony because (a) his specialized knowledge of healthcare analytics will help the trier of fact to understand the voluminous claims data relevant to this case; (b) his testimony is based on extensive facts and data; (c) his testimony is the product of reliable principles and methods; and (d) he has reliably applied the principles and methods to the facts of the case. Fed. R. Evid. 702; *see also MEDARC, LLC v. Scott & White Health Plan*, 618 F. Supp. 3d 365, 370 (N.D. Tex. 2022). Here, the issues to be decided by the Court under Rule 702 are whether Russo relied on sufficient data and whether his testimony is the product of reliable methods. ECF 457 at 13-23. The answer to both questions is yes.

Notably, Relator does not contest Russo’s qualifications to serve as an expert in this case. And indeed, she could not plausibly do so. Russo received a master’s degree in Health Finance and Management from the Johns Hopkins Bloomberg School of Public Health and he is a member of the Healthcare Financial Management Association. ECF 456-1, APP. 560-563 (Amended Expert Report of Gregory Russo (hereinafter Russo Report)). Russo is a Managing Director in the Health Analytics practice of Berkeley Research Group, LLC, and he has extensive experience in analyzing claims data for physician groups, hospitals, and health systems. *Id.* Moreover, Russo has published numerous articles and presented on issues relating to healthcare data analytics, the Medicare program, and the False Claims Act, and served as an expert in a variety of other federal and state court cases applying a

similar methodology and approach to data analysis. *Id.*, 563-569 (Russo Report).

Nor does Relator contest that this case involves vast troves of claims data that will need to be organized to assist the factfinder in understanding HCAT's practices. It is well-established that data analytics experts can assist juries by summarizing large volumes of data. *See, e.g., Hafen v. Howell*, No. 2:19-CV-00813-TC-DAO, 2023 WL 2188566, at *4 (D. Utah Feb. 23, 2023) (finding that expert's "complex data analyses" would be helpful "in assisting the trier of fact [to] understand [] complex business activities and records"). In another FCA case, *United States ex rel. Bahnsen v. Bos. Sci. Neuromodulation Corp.*, No. CV 11-1210, 2017 WL 6402633 (D.N.J. Dec. 15, 2017), Russo analyzed relevant claims data and excluded claims which the relator's expert had opined were false. In ruling on the relator's Rule 702 motion that Russo's testimony was unreliable and impermissible, the court ruled that so long as Russo did not provide a legal conclusion as to what constitutes a "claim," his testimony could assist the trier of fact stating that: "[s]imilar to how Federal Rule of Evidence 1006 allows summary witnesses to testify on the contents of voluminous writings, recordings, and photographs, the Court will allow Russo []to testify to factual details based on the data available and explanations about claims." *Id.* at *4. Similarly here, Russo will help the jury organize and make sense of the amass of claims data produced by HCAT and Novitas in this matter.¹⁵ HCAT produced all claims data that were potentially relevant to Relator's allegations during the applicable time period, resulting in the production of thousands upon thousands of claim lines reflecting patient encounters, bills, diagnoses insurance information, among other pertinent data points. And, throughout the time period at issue, HCAT used three electronic health record (EHR) and billing systems to store its data, adding further complexity.¹⁶ Yet these data will play a critical role in the evaluation of several primary allegations by

¹⁵ Claims data was produced in this matter by Novitas, the Medicare Administrative Contractor for Texas. *See* ECF 456-1, APP. 527 (Russo Report).

¹⁶ Allscripts (2015-2019), eClinicalWorks ("ECW") (2018-2022), and NextGen (2017-2020). *See* ECF 456-1, APP. 528 (Russo Report).

Relator in this matter highlighting the importance of ensuring the jury can process and digest the data. Russo has extensive experience doing just that.

A. Russo's testimony is based on sufficient facts or data.

Relator's objections to the use of the HCAT billing data goes to the weight of the evidence, not its admissibility. *Viterbo v. Dow Chem. Co.*, 826 F.2d 420, 422 (5th Cir. 1987) ("As a general rule, questions relating to the bases and sources of an expert's opinion affect the weight to be assigned that opinion rather than its admissibility"); see *Wellogix, Inc. v. Accenture LLP*, 788 F. Supp. 2d 523, 538 (S.D. Tex. 2011) (rejecting exclusion of expert based on documents relied upon and reserving such issues for cross-examination). While Rule 702 has been amended to clarify that experts must demonstrate a threshold level of experience and reliability before their opinion is admissible, it is still the case that "[s]ome challenges to expert testimony will raise matters of weight rather than admissibility." Fed. R. Evid. 702 advisory committee's note to 2023 amendment. Relator's objections to Defendants' experts are precisely the type of challenges that go to the weight, not admissibility, of their testimony. For example, while Defendants have pointed out that *Relator's experts* frequently opine on matters for which they have no reliable basis for their opinions whatsoever (*see, e.g.*, ECF 409), Relator simply contends that Russo primarily relied on one data set over another. ECF 457 at 18-19. To the extent that Relator contends that the internal HCAT billing data is less reliable than Novitas data, these issues can be explored during cross examination.

Even assuming Relator's objections with respect to Russo were the proper subject of a Rule 702 motion, they fail because Russo properly relied upon accurate and reliable data sets. HCAT's internal data is maintained by HCAT in the normal course of business, and, as discussed below, is the basis upon which all other claims data – including Novitas data – is created.

Nonetheless, Relator attempts to discredit Russo's methodology by claiming that Russo's use of HCAT data was improper, and Relator incorrectly argues that Russo failed to consider Novitas data

or the medical records in his analysis. Relator boldly alleges — with no underlying support — that HCAT’s internal data is “error-filled” and “demonstrably manipulated,” and thus cannot be meaningfully relied upon. *See* ECF 457 at 14. These allegations are patently untrue and the slender reed upon which Relator’s entire argument rests.

First, as Russo explained in his report and during his deposition, he used both the Novitas data and HCAT internal data. *See* EF 456-1, APP. 890 (Russo Tr. at 23:14-24:20). The HCAT data had a “high amount of consistency with the data that Ms. Scott relied upon and the Novitas data with respect to the billing and rendering physicians/providers.” ECF 456-1, APP. 889 (Russo Dep. Tr. at 19:4-9). In fact, Russo testified that those data sets had a near 99% consistency rate in providers across datasets. *See id.* (Russo Tr. at 19:15-19); ECF 456-1, APP. 528 (Russo Report at 8).¹⁷ Besides, Novitas data is sourced directly from HCAT’s data, so any assertion that HCAT’s data is unreliable or manipulated is akin to a claim that the Novitas data is similarly unreliable or erroneous, making no one more reliable than the other. *See* ECF 456-1, APP. 932 (Russo Tr. at 19:13-19); ECF 457 at 14 n.100.

Relator boldly claims that “HCAT did not certify the accuracy of [its] internal data,” implying both that HCAT’s data is inaccurate and that HCAT should have, but failed to, certify the accuracy of its data. ECF 457 at 15. There is no requirement to “certify” the data, and regardless, HCAT has continuously maintained the accuracy and reliability of its internal data. Relator again questions the accuracy of HCAT’s data by noting that “[u]nlike the progress notes, internal billing data are not required by law to be accurate.” *Id.* at 15-16. Relator’s implications are nonsensical, because the source of HCAT’s internal data is from the EHR systems where the medical records are stored. *See* Russo

¹⁷ This is consistent with what is seen in the healthcare industry. For example, the Centers for Medicare and Medicaid Services (CMS) licenses Medicare claims data to researchers, and this data represents 99% of Medicare FFS claims due to claims. The claims data reflects approximately 99% of claims even when produced in their “final” form. *See* **App. 455-458** (HHS, Guidance Portal, Fee-for-Services (FFS) Quarterly Data FAQs, available at <https://www.hhs.gov/guidance/document/fee-service-ffs-quarterly-data-faq>). *See also* EF 456-1, APP. 891 (Russo Dep. Tr. at 26:15-27:10).

Report at 7 (“the HCAT data comes from the EHR systems”).

Second, Relator’s claims that HCAT’s internal data was “manipulated” between the beginning and end of discovery is simply unfounded. HCAT produced several iterations of its data in this case in efforts to ensure that all relevant data was ultimately produced, and in doing so, conducted data refreshes to ensure that the data it was providing was accurate and up-to-date. Relator points to these data refresh exercises as providing an example of HCAT data “manipulation,” pointing to one example involving a patient (D.E.), who, according to the progress notes from their visits, was there “to follow up on PEP physical test results.” ECF 457 at 17-18. As Relator noted, HCAT’s January 28, 2022 data production reflected that this encounter was a PEP visit, while its February 6, 2024 replacement data indicated that this encounter was something else. *Id.* In a “gotcha” fashion, Relator claims that this was a “PEP” claim and thus the original data production was accurate, supporting its claim that HCAT intentionally manipulated its data. Relator then expresses “shock” that Russo was unmoved when confronted with this evidence. *Id.* at 18.

Yet contrary to Relator’s assertion, the refreshed data reproduced in 2024 is accurate. As has been explained in detail by Defendants’ experts in this case, the PEP program typically consists of a two day process: the first encounter involves a questionnaire soliciting information for the annual wellness visit and tests conducted on patients pursuant to protocolized orders depending on a patient’s active diagnoses, medical history, and other patient characteristics (Day 1), while the second encounter involves a meeting with a physician to review the results of the tests conducted (Day 2). Day 1 encounters are billed as PEP claims, while Day 2 encounters are billed as physician visits. As Relator clearly acknowledges in its report (ECF 457 at 18, citing Russo Ex. 6 (HCAT_TAYLOR_3581674) (ECF 456-1, APP. 01163)), this patient visit was to ***follow up*** on PEP physical tests results, indicating that this was a Day 2 visit with a physician. HCAT’s data thus accurately reflects the encounter, supporting Defendants’ contention that it reproduced refreshed data in efforts to ensure that accurate,

up-to-date data was produced in this case, and not for purposes of manipulating or falsifying data.

Third, Relator neglects to address the key legitimate reasons why Russo relied on the HCAT data. As explained in Russo's report, there are more data fields available in the HCAT data that are not collected by Novitas. *Id.*, at APP. 527. The Novitas data omits key information that is exclusively stored in the HCAT internal data and is necessary to adequately assess some of the primary issues involved in this case, including the accuracy of claims billed incident-to and the identification of PEP claims. For example, whereas the HCAT data identifies the provider who performed the service billed, the Novitas data identifies the provider under which the claim is being billed, which is not always the provider who performed the service, such as in the case of incident-to billing. *Id.* Thus, reliance on the HCAT data was necessary in order to accurately identify the provider who performed the service.

B. Russo's methodology is reliable.

The inquiry into whether an expert testimony is relevant and reliable is inherently flexible and "the judge has discretion in determining which [*Daubert*] factors are most germane in light of the nature of the issue, the particular expertise, and the subject of the expert's testimony." *United States v. Valencia*, 600 F.3d 389, 424 (5th Cir. 2010). Expert testimony should only be excluded if it is highly speculative or if it is based on assumptions that are so unrealistic and contradictory as to suggest bad faith. *See, e.g., Feliciano v. CoreLogic Saferent, LLC*, No. 17 CIV. 5507 (AKH), 2020 WL 6205689, at *2 (S.D.N.Y. June 11, 2020). That is not the case with Russo's opinions. Here, a cursory review of academic papers and court decisions demonstrates the prevalence of complex data analysis conducted by professionals like Russo who reach conclusions and opine based on their education, experience, and review and analysis of large data sets. In addition, Russo's analyses are all entirely replicable, with all materials and information needed to replicate these analyses produced, a key component to the

scientific method.¹⁸

As a threshold matter, Relator's contention that Russo's method "makes no sense" (ECF 457 at 21) goes to the weight, not the admissibility, of the testimony. *14.38 Acres of Land*, 80 F.3d at 1077. As the Fifth Circuit has explained, "[a]s a general rule, questions relating to the bases and sources of an expert's opinion affect the weight to be assigned that opinion rather than its admissibility and should be left for the jury's consideration." *United States v. Hodge*, 933 F.3d 468, 478 (5th Cir. 2019), *as revised* (Aug. 9, 2019). Even if Relator's contention were appropriate for a Rule 702 motion, its arguments fail. Relator's challenges seem to be focused only on Russo's methodology as applied to his determination of whether incident-to billing requirements were met, and does not challenge any other methodology applied by Russo throughout his report. Russo identified whether incident-to billing requirements were met by following a detailed process outlined in his report. *See* ECF 456-1, APP. 542-543 (Russo Report). One of the criteria that Russo considered was whether the Medicare beneficiary had been seen for the same condition previously by a physician, which he determined by evaluating the first three digits of all available diagnosis codes ("the diagnosis code family") on the incident-to claim to see if there was a claim for a visit with a physician as the rendering provider with the same diagnosis code family over the past three years (hereinafter the "diagnosis codes methodology"). *Id.* As described his report, this was a reasonable and well-supported methodology rooted in Russo's extensive expertise in analyzing healthcare claims of this nature.

Rather than point to evidence demonstrating that this methodology does not comport with the "incident to" regulation itself, or resulted in any incorrect determinations by Russo, Relator's offers only *hypothetical* criticisms of Russo's methodology, reflecting a *reductio ad absurdum* line of

¹⁸ The same cannot be said of analyses put forth by Relator's experts. *See* ECF 456-1, APP. 530-531 (Russo Report at 10-11 (discussing errors in Nicholas Ross's expert report preventing replication)).

reasoning.¹⁹ Specifically, Relator tries to discredit Russo's diagnosis codes methodology by claiming diagnosis code families "need not be connected in any way" (ECF 457 at 21) using two hypothetical examples of claims that it alleges the diagnosis code family methodology would incorrectly identify as being part of the same course of treatment and thus ripe for incident-to billing. Relator alleges this method would determine that that a patient's visit in 2020 for a broken left arm is part of the same course of treatment as an earlier visit in 2018 for a broken right clavicle, and that a patient visit in the winter of 2016 for strep throat would be part of a single course of treatment as a 2019 visit for strep throat. ECF 457 at 21-22. Relator implies, with no clinical support, that these examples could simply never reflect incident-to claims. *Id.* Relator ignores that HCAT's clinical expert, Dr. Shapiro, said the opposite. Dr. Shapiro agreed with this methodology and conformed that it is reasonable to use diagnosis code families to identify claims related as part of the same course of treatment:

Q. Do you believe that if a patient is being seen on two different visits for the same condition that they are automatically part of the same course of treatment?

A. I think that's a reasonable assumption that if a patient is seen for the same condition on two separate visits, that the second visit should be considered part of the course of diagnosis and treatment for that condition.

ECF 456-1, APP. 1286 (Shapiro Dep. Tr. at 129:15-23); *see also id.* APP. 1290 (Shapiro Dep. Tr. at 141:11-19) ("I believe it was reasonable for Mr. Russo to determine that if the two -- if the diagnosis at the initiating visit and the second visit, the incident-to visit, are the same or are closely related by virtue of the fact that they're in the same diagnostic category, that it is reasonable to assume that the course of diagnosis and treatment is the same for those condition -- for those two conditions."); *id.* APP. 1291 (Shapiro Dep. Tr. at 142:18-143:1). Dr. Shapiro even considered Relator's broken-arm-

¹⁹ *See, e.g.*, ECF 456-1, APP. 932 (Russo Dep. Tr. at 186:13-22) ("Q. Okay. So let me change the hypothetical. Would your -- would your script treat two encounters two years apart with separate -- different providers but both involving strep throat as incident to for the purpose of having a single course of treatment? A. So let's first be clear we are talking about a hypothetical. We don't actually know if this strep throat claim exists in the data. Q. Sure.).

broken-clavicle hypothetical and testified that it was reasonable to use diagnosis code families because those injuries are “both considered part of the shoulder.” *Id.* APP. 1290 (Shapiro Dep. Tr. at 138:2-13). Notably, Relator does not challenge Dr. Shapiro’s expert testimony in this case.

Relator’s reductive characterization of diagnosis codes reflected both in its Rule 702 motion and in deposition questioning, overlooks the fact that there are tens of thousands of highly specific and standardized diagnosis codes, created by the World health Organization, and adopted by CMS annually. *See* ECF 456-1, APP. 1258 (Shapiro Dep. Tr. 10:12-11:13). The fact that an individual was diagnosed with two conditions within the same diagnosis code family within a certain period of time in fact lends a strong likelihood that those conditions are connected or related. Moreover, the determination of whether a patient’s condition meets the criteria for a particular diagnosis code requires clinical judgment. Similarly, the determination of whether a particular diagnosis reflects an ongoing or continuous course of treatment is likewise subject to clinical judgment. *See, e.g.*, ECF 456-1, APP. 1266 (Shapiro Dep. Tr. at 43:9-14) (“If a patient is in chronic atrial fibrillation and it’s not treated at all, they may or may not be at risk for developing certain complications. Whether they need treatment and what that treatment should be is something that the physician has to determine.”). Regardless, the incident-to regulation itself expressly ties the services to a “course of diagnosis or treatment of an injury or illness”, which is exactly what healthcare diagnosis code families capture. *See* 42 C.F.R. § 410.26(b)(2).

CONCLUSION

For the foregoing reasons, Defendants respectfully request that Relator’s Motion to Exclude Defendants’ experts be denied in its entirety.

Dated: September 16, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that, on September 16, 2024, a true and correct copy of the foregoing document was filed with the Clerk of Court via the CM/ECF system, causing it to be served electronically on all counsel of record.

/s/ Elizabeth Brandon

Elizabeth Brandon